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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/551,192

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Eiichi Kitazono

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EXAMINER

PALENIK, JEFFREY T

ART UNIT

PAPER NUMBER

1615

NOTIFICATION DATE

DELIVERY MODE

05/19/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/551,192	Applicant(s) KITAZONO ET AL.	
	Examiner Jeffrey T. Palenik	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,6-8 and 10-14 is/are pending in the application.
- 4a) Of the above claim(s) 1,2,4,6 and 12-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7,8,10 and 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>26 Apr 2010</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

STATUS OF THE APPLICATION

Receipt is acknowledged of Applicants' Amendments and Remarks filed, 24 February 2010 in the matter of Application N° 10/551,192. Said filings are entered on the record. The Examiner further acknowledges the following:

No claims have been added. Claim 9 has been canceled.

Claims 7 alone has been amended to with the limitations of the canceled claim 9, namely that the fiber structure is "made of an aliphatic polyester". Concerning this amendment, the Examiner recognizes that Applicants have sufficient support given that the limitation was previously recited in claim 9. However, Applicants are respectfully warned that all amendments to any claim must comply with MPEP §714. It seems to the Examiner that this was simply a typographical error.

The remaining amendment to claim 7 adds the limitation of "a mean fiber size of 0.3-10 μm " to the claim. Applicants' support is sufficient.

No new matter has been added.

Thus, claims 7, 8, 10 and 11 now represent all claims currently under consideration.

INFORMATION DISCLOSURE STATEMENT

One new Information Disclosure Statement (IDS) filed 26 April 2010 is acknowledged and has been considered.

NEW REJECTIONS

In light of Applicants' forgoing amendment to the base claim, the following rejection is newly presented:

CLAIM REJECTIONS - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants' amendment to claim 7 recites a "mean fiber size" which is narrower in diameter (e.g. 0.3-10 microns) than that which is recited in claim 11 (e.g. 0.5-50 microns). The scope of the invention is thus rendered indefinite. Given the discrepancy between fiber sizes, the limitation continues to be broadly and reasonably interpreted in light of the disclosure as reciting a fiber size of 0.5-50 microns, for the purposes of examination on the merits.

MAINTAINED REJECTIONS

The following rejections are maintained from the previous Office Correspondence dated 24 August 2009 since the art which was previously cited continues to read on the amended/newly cited limitations.

DOUBLE PATENTING

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 7-11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5, 6 and 8 of copending Application No. 11/791,115 (US Pre-Grant Publication N° 2007/0298072). Although the conflicting claims are not identical, they are not patentably distinct from those which are instantly recited because both the instant and copending compositions are obvious variants if not anticipatory of one another. The instant claim 7 recites a bellows-shaped cylindrical body comprising a membrane which is comprised of fiber structures. The membrane is recited as ranging from 0.05-0.2 mm in thickness (e.g. 50-200 microns). The cylindrical body is recited as having a diameter ranging from 0.5-50 mm (e.g. 50-50,000 microns). The bellows shape is recited as having a crest-to-crest distance of no more than 2.0 mm and a crest-to-valley depth ranging from 0.1-10 mm.

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Claim 11 recites that the mean fiber size (e.g. thickness) ranges from 0.05-50 microns. The same limitations are recited by claims 1 and 8 of the copending '115 application. The instant claims 8-10 recite compositional limitations to the fiber structure of claim 7 such that the fibers are made from biodegradable, aliphatic polyester polymers selected from polylactic acid, polyglycolic acid, polycaprolactone or a combination thereof. The same limitations are recited in claims 5 and 6 of the copending '115 application. Given that the compositions of both the copending and instantly claimed applications very closely parallel one another, it follows that one of ordinary skill in the art would have immediately recognized the obvious overlap in subject matter and would have been motivated with a high expectation of success, to prepare the instantly claimed composition.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

RESPONSE TO ARGUMENTS

Applicants' request that each of the forgoing rejections on the grounds of provisional nonstatutory obviousness-type double patenting over the respective teachings is held in abeyance until the pending claims are found to be allowable.

In response, the Examiner acknowledges Applicants' request and respectfully submits that each of the forgoing rejections will be **maintained** until such time as the claims are placed into condition for allowance.

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CLAIM REJECTIONS - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 7, 8, 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over the teachings of Schmitt et al. (USPN 3,463,158) [*emphasis added to reflect canceled claim*].

The instant claims are drawn to a cylindrical, bellows-shaped body comprising a fiber structure, as discussed above. Dimensions of the various aspects of the composition are also

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discussed above. Claims 8-10 further limit the material of the fiber to PLA, PGA, polycaprolactone and copolymers thereof (e.g. PLGA).

The invention of Schmitt is directed to polyglycolic acid prosthetic devices (Title). The dimensional limitations of claim 11 are expressly taught in Example 3 (col. 6, lines 47-52), whereby PGA is spun into fibers having a diameter of 0.002 inches or approximately 50 microns (see http://www.onlineconversion.com/length_all.htm). Thus, given that the upper limit of fiber thickness is expressly taught, the lower limit of the instantly claimed membrane thickness (e.g. 50 microns) is necessarily taught as well. This limitation is further considered by the Examiner as having been met particularly since Schmitt expressly teaches that the fibers which are prepared may be used to for tubes and thin solid sheets (col. 3, lines 4-5 and lines 59-65). The diameter dimension is expressly taught wherein the sheets and/or tube structures which are formed are further taught as having "at least one dimension greater than 2 millimeters, and which may have a dimension as great as about 200 millimeters" (col. 3, lines 8-10). Figures 10-14 depict a tube-shaped structure comprising ridges or ribs consistently throughout the entire composition. Example 6 is specifically directed to an arterial prosthesis prepared from a mixture of polyester and polyglycolic acid fibers wherein the resulting prostheses has an overall structural diameter of only 3/16 inches or approximately 4,760 microns (col. 10, lines 22-23). Thus, the Figures and Example expressly teach the bellow-shaped and diameter limitations of the instant claim 7. Figures 5-7 and 9 expressly teach the limitations of claims 8-10, such that the fiber structures are shown from different perspectives as being comprised of different percentages of polyglycolic acid.

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The reference, despite teaching the instantly claimed bellows-shaped design in the Figures showing the arterial prostheses, does not expressly teach the instantly claimed peak-to-peak or peak-to-valley dimensions.

However, it would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to have optimized such dimensions, particularly in view of teachings such as Figures 1-7, 9 and 15. Since the values and formats of each parameter with respect to the claimed composition (e.g. fiber thickness) are adjustable, it follows that each is a result-effective parameter that a person having ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. In the instant case, Schmitt expressly teaches in Example 3 that the fibers are spun to a preferred thickness of approximately 50 microns. However, per MPEP §2123 (II), preferred teachings provided in the art do not necessarily constitute a teaching away from the instant claims. As such, it would have been customary for an artisan of ordinary skill, to adjust the filament thickness of the constituent fibers in order to achieve the desired amplitude and frequency dimensions as instantly recited. Thus, absent some demonstration of unexpected results from the claimed parameters, optimization of any of these parameters would have been obvious at the time of Applicants' invention.

Furthermore, based on the express teachings of the reference, it is apparent that one of ordinary skill in the art would not only have been highly motivated to produce the instantly claimed composition, but would also have had a reasonably high expectation of successfully doing so. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in

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the art at the time the invention was made, as evidenced by the references, alone or in combination, especially in the absence of evidence to the contrary.

RESPONSE TO ARGUMENTS

Applicants' arguments with regard to the rejection of claims 7, 8, 10 and 11 under 35 USC 103(a) as being unpatentable over the teachings of Schmitt et al. have been fully considered but they are not persuasive.

Applicants allege that the "invention as recited in the amended claims is not obvious over Schmitt" and further traverses the reference on the grounds that it and the instant invention employ distinct methods of production.

In response, the Examiner respectfully disagrees and submits that Applicants' amendments have not helped to distinguish over the art. Rather Applicants' amendment has raised issues of indefiniteness under the second paragraph of 35 USC 112, as discussed above. Further, Applicants' arguments concerning the distinct manufacturing methods is irrelevant for two reasons, the more compelling of which is that no method limitations appear within the instant claims. Secondly, the instant invention is directed to a composition rather than its method for producing said composition. Absent a clear showing of evidence to the contrary, said method limitations would be considered as product-by-process limitations (MPEP §2113).

For these reasons, Applicants' arguments are found unpersuasive. Said rejection is therefore **maintained**.

All claims have been rejected; no claims are allowed.

CONCLUSION

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

CORRESPONDENCE

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey T. Palenik whose telephone number is (571) 270-1966. The examiner can normally be reached on 7:30 am - 5:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

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may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey T. Palenik/
Examiner, Art Unit 1615

/Robert A. Wax/
Supervisory Patent Examiner, Art Unit 1615